REMARKS

Claims 1 to 105 are pending in the instant application. The present Office Action includes a Request for Restriction, a response to which is discussed herein.

The Examiner has requested a restriction to one of the following groups:

I. Claims 1 -42, drawn to a composition comprising (1) an ionizable pharmaceutical agent; (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free.

II. Claim 44-95, drawn to a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and (3) wherein the composition is substantially sugar-free.

III. Claim 96, drawn to a method for the oral transmucosal delivery of a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and 94) wherein the composition is substantially sugar-free comprising.

IV. Claim 97, drawn to a method for the oral transmucosal delivery of a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and 93) wherein the composition is substantially sugar-free.

V. Claims 98-101, drawn to a method of treating pain comprising introducing a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free comprising into the oral cavity of an individual.

VI. Claims 102-104, drawn to a method of treating pain comprising introducing a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient and (3) wherein the composition is substantially sugar-free comprising into the oral cavity of an individual.

Restriction is only proper if the restricted inventions are independent and patentably distinct (35 U.S.C. §121) and there is a serious burden placed on an Examiner if restriction is not required (MPEP 803). The burden is on an Examiner to provide

reasons and/or examples to support any conclusions of patentable distinctness between the restricted inventions (MPEP 803). Applicants respectfully traverse the Restriction Requirement on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the restricted inventions and that no serious burden is placed on the Examiner if restriction is not required.

The Examiner asserts that the compositions of Groups I and II are patentably distinct from the methods of Groups III-VI because the compositions as claimed can be used in a materially different manner. Applicants respectfully traverse on the grounds that compositions of Groups I and II, which are "oral transmucosal solid dosage forms", and the methods of Groups III-VI, which are methods of oral transmucosal delivery, share a similar utility, the oral transmucosal delivery of drugs. Thus, the six groups should not be construed as separate and distinct inventions.

The Examiner asserts that the compositions of Groups I and II are patentably distinct because the compositions as claimed have different modes of operation, effects, and functions. Applicants respectfully traverse on the grounds that compositions of Groups I and II, are structurally similar, in that they both comprise an ionizable pharmaceutical agent (eg. fentanyl), a pharmaceutically acceptable excipient (eg polyhydric alcohol), and the sugar-free characteristic. Additionally, they are both oral transmucosal dosage forms, thus they share the same operation. Additionally, they may both contain a buffer. Thus, the two groups should not be construed as separate and distinct inventions, but rather more similar to a genus-subgenus relationship.

Applicants hereby reserve the right to prosecute the claims encompassed by any of the non-elected groups in future divisional applications.

Applicants furthermore request that should any claims of Group I be found allowable that the claims of Group III-VI be considered for rejoinder.

Conclusion

For the above reasons, Applicant submits that the restriction by the Examiner is improper and request that the restriction be withdrawn or reconsidered.

Respectfully submitted,

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